4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0175]

Determination That LYMPHAZURIN (Isosulfan Blue) Injectable and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Amy Hopkins, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6223, Silver Spring, MD 20993-0002, 301-796-5418, Amy.Hopkins@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants

do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed. (As requested by the applicants, FDA withdrew approval of NDA 018310 for LYMPHAZURIN (isosulfan blue) Injectable in the Federal Register of December 5, 2014 (79 FR 72186) and NDA 020151 for EFFEXOR (venlafaxine HCl) Tablets in the Federal Register of July 19, 2013 (78 FR 43210).)

Application No.	Drug	Applicant
NDA 018310	LYMPHAZURIN (isosulfan blue) Injectable; Injection, 1%	Covidien, 60 Middletown Ave., North Haven, CT 06473
NDA 019966	TEMOVATE (clobetasol propionate) Solution; Topical, 0.05%	Fougera Pharmaceuticals Inc., 1 Health Plaza, Bldg. 434, East Hanover, NJ 07936
NDA 020151	EFFEXOR (venlafaxine hydrochloride (HCl)) Tablet; Oral, Equivalent to (EQ) 12.5 milligram (mg) Base; EQ 25 mg Base; EQ 37.5 mg Base; EQ 50 mg Base; EQ 75 mg Base; EQ 100 mg Base	Wyeth Pharmaceuticals Inc., 235 East 42nd St., New York, NY 10017
NDA 020214	ZEMURON (rocuronium bromide) Injectable; Injection 100 mg/10 milliliter (mL); 50 mg/5 mL; 10 mg/mL	Organon USA Inc., 351 North Sunmeytown Pike, North Wales, PA 19454
NDA 021040	PREFEST (estradiol; norgestimate) Tablet; Oral, 1 mg, 1 mg/0.09 mg	Teva Branded Pharmaceutical Products R&D, Inc., 41 Moores Rd., P.O. Box 4011, Frazer, PA 19355
NDA 021621	CHILDREN'S ZYRTEC ALLERGY (cetirizine HCl) and CHILDREN'S ZYRTEC HIVES RELIEF (cetirizine HCl) Chewable Tablet; Oral, 5 mg; 10 mg	McNeil Consumer Healthcare, 7050 Camp Hill Rd., Fort Washington, PA 19034
NDA 050783	PERIOSTAT (doxycycline hyclate) Tablet; Oral, EQ 20 mg Base	Galderma Laboratories, L.P., 14501 North Freeway, Fort Worth, TX 76177

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the "Discontinued Drug Product List" section of the Orange Book. The

"Discontinued Drug Product List" identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: January 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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